Manual for Methadone Medical Management

David A. Fiellin, M.D.
Michael V. Pantalon, Ph.D.
Patrick G. O'Connor, M.D., M.P.H.

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The following individuals contributed significantly to the development of this manual and provided comments on earlier versions:

Richard J. Bilangi, M.S.
Michael Feinberg, M.D.
Michael Freeman, M.S., C.D.A.C., M.A.C., C.C.S.
Mark Kraus, M.D.
Richard Shottenfeld, M.D.

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MANUAL FOR MEDICAL MANAGEMENT OF METHADONE MAINTENANCE TREATMENT

I. AIMS OF MEDICAL MANAGEMENT (MM)

A. General Aims & Overview

The aim of this manual is to describe the procedures involved in the delivery of Medical Management (MM) of methadone maintenance treatment. The manual was designed for routine use by a trained physician in a primary care setting. It describes the general and specific aims of MM and details a structured format for conducting the individual components of MM.

MM is a manual-guided, medically-focused approach to treatment of opiate dependent individuals. MM is designed for patients who are stable and have been doing well for a long period of time in a standard methadone program, as evidenced by sustained abstinence from illicit drugs and good social functioning. In addition to increased flexibility and responsibility for their treatment, the patient in MM will benefit from receiving care for their opiate dependence in a less stigmatizing environment with and with fewer contacts with recovering illicit drug users. By providing a more medically focused orientation, the goal of MM is to recreate a model used by primary care practitioners for the management of a number of diseases including diabetes, hypertension, and coronary artery disease. The role of the primary care physician in the management of these diseases often includes monitoring of compliance with medication and lifestyle modifications, assessment of symptoms related to the disease process or medication, and education regarding the disease process and treatment. In this role, physicians utilize focused interactions with patients to augment the role of medication. In a like manner, MM for opiate dependent patients is designed to provide support for the patient's efforts to remain abstinent and compliant with medication.

This manual contains general and specific information and should be used as a reference by those who are providing medical management with methadone. The goal is to provide the reader with an overview and rationale for the skills needed to provide medical management of opiate dependent patients with methadone in a primary care setting. The material is designed to be augmented by didactic sessions, additional references, and practice cases to assist trainees in providing medical management of opiate dependent patients.

B. Specific Aims of MM

1. Support patient's efforts to remain abstinent.
2. Monitor abstinence (i.e., urine toxicology results and patient report).
3. Monitor the administration of and compliance with methadone

4. Discuss attendance at self-help groups (i.e., NA or AA) in those patients who have found these helpful.

II. PROTOCOL FOR MEDICAL MANAGEMENT

In order to accomplish the goals of MM and to provide a rational and structured organization to the sessions, the following sections will present both a general structure and a detailed description, of specific procedures for the initial and subsequent MM sessions. Once trained in MM, the reader will be able to use the manual as a guide when administering the components of the treatment. The outline format for the two “Specific Procedures” sections of the "Patient Care Sessions" (i.e., initial and subsequent sessions) is meant to be used as a quick reference for the physician and as a “checklist,” which can help to ensure that all of the required treatment components are covered in a given visit.

A. Physician's role and responsibilities

The following list contains the core responsibilities for physicians providing MM from their office.

The following components must be completed prior to enrolling the first patient in MM.

1. Participate in initial training sessions.
2. Obtain and maintain a Federal DEA license for dispensing of methadone for maintenance therapy.

The following components are ongoing and comprise clinical care under MM.

3. Perform initial study visit (45-50 minutes) to review medical and psychiatric history of subjects referred to their office for methadone maintenance treatment, including determination of appropriateness.
4. Prescribe methadone for subjects assigned to their office.
5. Meet weekly with patients to observe ingestion of one dose of methadone and provide weekly supply of methadone for patient to take home. Note: This function may be performed by a nurse under the supervision of the responsible physician.
6. Perform monthly follow-up visits (30 minutes) with patients to provide counseling.
7. Maintain ongoing patient problem list and update "Treatment Plan Review" accordingly.
8. Monitor patients for evidence of clinical deterioration including evidence of new substance abuse.
9. Assure appropriate transfer of subjects to Connecticut Counseling Centers, Inc. when necessary or at end of study.

The following components comprise the administrative responsibilities of MM

10. Supervise maintenance of onsite methadone bottle log.

11. Meet monthly with research physician to review patients and perform quality review.
12. Provide supervision to office staff who interact with patients.
13. Complete appropriate research and clinical documentation for study subjects.

Each responsibility will be discussed in detail in the section that follows.

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1. Participate in initial training sessions.
   Two one-half day training sessions constitute the initial training for office-based MM. These sessions include information on the history, pharmacology, and effectiveness of methadone maintenance therapy. In addition, didactic and case-based discussions will cover counseling, dispensing, administrative issues, and medical care for patients on methadone. These required sessions are designed to provide physicians with the "basic science" required for the care of patients on methadone maintenance.

2. Obtain and maintain a Federal DEA license for dispensing of methadone for maintenance therapy.

In order to provide methadone to patients enrolled in the project, it is necessary for all physicians to obtain and maintain a Federal DEA license that allows for the dispensing of methadone for maintenance therapy. The project's supervising physicians will assist each physician with this process and paperwork.

3. Perform Initial/Intake Session (45-50 minutes)

<u>Specific Procedures for Initial MM Session</u>

a. Review medical, psychiatric, and substance abuse history
b. Review specific complications of substance abuse
c. Develop treatment plan and offer rationale for each component (including methadone maintenance and MM visits)
d. Discuss unique features of the program
e. Discuss the role of self-help groups (NA, AA) in the patient's recovery
f. Advise abstinence from all drugs
g. Answer patient's questions
h. Dispense medication

Please see "Patient care sessions" section of this manual for descriptions of each of the listed components

1. Prescribe methadone for subjects assigned to their office.

Physicians involved in this pilot project will provide MM in their offices to Connecticut Counseling Centers, Inc.(CCCI) patients as medical consultants to CCCI. As medical consultants to CCCI, MM physicians will be responsible for prescribing methadone to the patients assigned to their office, including changes in methadone dose.

2. Meet weekly with patients to observe ingestion of one dose of methadone and provide weekly supply of methadone for patient to take home. Note: This function may be performed by a nurse under the supervision of the responsible physician.

   Each week patients assigned to MM will receive methadone in their physician's office. Protocols (see Treatment protocols) will be tailored to each site to allow for efficient and safe transfer of methadone bottles from office staff to the patient. Office staff will 1) accept empty methadone bottles from the patient, 2) log receipt and condition of these bottles in the appropriate onsite log book 3) observe the ingestion of one dose of methadone and 4) provide the patient with a weekly supply of methadone bottles. Particular attention during these visits should be paid to evidence of clinical instability and the physician should be notified if there are questions or concerns over the patients condition.

3. Perform monthly follow-up visits (30 minutes) with patients to provide counseling.

Specific Procedures

a. Ask about Heroin/cocaine or other illicit drug use since last visit
b. Assess for symptoms or signs that might imply relapse
c. Review potential problem areas
d. Record new problems for Treatment Plan Review
e. Record plan for any new problems
f. Review treatment plan (Methadone, Abstinence, NA or AA participation)

See "Patient care sessions" section of this manual for discussion of the content for these sessions.

1. Maintain ongoing patient problem list and update "Treatment Plan Review" accordingly.

As part of their care at CCCI each patient has a Treatment Plan Review that constitutes an ongoing record of their active medical, psychiatric and psychosocial issues. This document provides a record of new issues or diagnoses along with a plan for monitoring or treatment. New diagnoses and issues to be addressed will be recorded in the appropriate section of the MD Progress Note (Appendix A)

2. Monitor patients for clinical deterioration including evidence of new substance use.

One of the primary responsibilities of the MM physician will be to ensure the safety and stability of all patients under their care. In addition to urine, breath, and hair toxicology monitoring which will occur on a regular basis, physicians will need to maintain a level of vigilance for symptoms or signs of relapse. Therefore, repeated interactions with the patient for formal and informal clinical assessment is essential to the safe conduct of MM. Awareness and recognition of psychosocial stressors and relapse triggers will help the physician maintain their therapeutic alliance and monitor for conditions that may represent or portend relapse to illicit drug use.

3. Supervise maintenance of onsite methadone bottle log.

Tracking of each dose of methadone is mandatory for compliance with federal regulations for dispensing of methadone. Therefore, each site will maintain a log to be used to catalogue the receipt and dispensing of methadone within the office. Standardized forms (See Appendix B) will be provided to assist with these procedures. While other office personnel may maintain these logs, the ultimate responsibility for completeness and accuracy will be that of the MM physician.

4. Provide supervision to office staff who interacts with patients.

MM will undoubtedly represent a new procedure for the physician's office. Therefore MM physicians will be responsible for supervising the care of the patients assigned to their office. In addition to clinical care and administrative oversight, physicians must be alert for any counter therapeutic climate that may develop in their office. The attitudes of nurses and staff who interact with methadone maintained patients are key to the successful care of these patients in any setting. Societal biases and misinformation regarding the role of agonist therapy in the care of opiate dependent patients may result in overt and covert experiences of discrimination for the patient. Physician supervision is essential to monitor and rectify problematic situations. Education of office staff and modeling of desired behaviors are key components to these tasks.

5. Meet monthly with project coordinating physicians to review patients and perform quality review.

Project coordinating physicians will meet monthly with MM physicians to review the status of all patients assigned to their site. Individual cases will be discussed and clinical scenarios reviewed. In addition, there will be discussion of illustrative or problematic cases from other MM sites to ensure appropriate dissemination of information. These ongoing quality improvement sessions are designed to supplement the initial educational sessions and are an integral component of physician training for MM.

6. Complete appropriate research and clinical documentation for study subjects.

Required documentation for MM patients includes the initial intake session note, monthly MD Progress Note, Treatment Plan Review and periodic assessments of physician satisfaction with MM.

7. Assure appropriate transfer of subjects to CCCI when necessary or at end of study.

In the event that a patient assigned to MM clinically deteriorates and requires transfer of methadone maintenance back to CCCI, the MM physician is responsible for overseeing this process and contacting one of the supervising program physicians (Drs. Fiellin, O'Connor or Schottenfeld), the Medical Director of CCCI, and the Program Director of CCCI. This will require completion of appropriate paperwork and an updated Treatment Plan Review. At the completion of the project, physicians will be responsible for transfer of the subjects to CCCI as outlined in section II D.

B. Patient Care sessions

1. Initial patient session

General Structure

In general, the initial session should be an effort by the physician to familiarize themselves with the patient's past medical history and prior substance abuse treatment history.

In addition, this will be a good opportunity to discuss with the patient the reasons for transfer of methadone dispensing to the physician's office and assess for any concerns that the patient may have. Although MM will provide patients with an opportunity to receive methadone in a novel setting, one should expect some degree of hesitancy from a patient who has been doing well for a long period of time at a methadone clinic setting and who has an established relationship with a drug counselor. It will be useful to include in this session some discussion of the patient's adherence to treatment to date, consideration of the advantages of coming to the physicians office (convenience, access, potential for increased flexibility) and provide support for the patient's efforts to maintain abstinence.

In the following section, each component of the "Specific Procedures" for the initial MM session will be discussed in further detail.

a. Review medical, psychiatric, and substance abuse history

After reviewing the intake packet from Connecticut Counseling Centers, Inc., which includes background information on current treatment, the physician reviews with the patient his/her medical, psychiatric, and substance abuse history. The physician should clarify for reinforcement any significant and positive findings.

The structure of this session should attempt to follow the model of a diabetic patient who might be transferring their care to your office after initial intensive care and stabilization by an endocrinologist. Initially the physician should have as their goal reviewing salient features of the patient's opiate dependence and treatment. In this manner, the physician should briefly review the patient's opiate dependence with consideration of onset, course, and prior treatment episodes. Next the physician should review the recent treatment history including the good track record with methadone maintenance, changes in frequency of contact with program and drug counselors (duration of weekly take home privileges and monthly drug counseling), record of negative urine results, and participation in self-help groups. Included in this should be an assessment of the patient's understanding of opiate dependence, the treatment, and what things have helped them maintain abstinence for so long. This may be a good opportunity to discuss therapeutic approaches that have been helpful for the patient and what the patient thinks they need at this point in their treatment. It may also be worthwhile to discuss with the patient their current dose of methadone and their level of comfort with that dose.

b. Review physical complications of substance abuse

Physicians should review with their patients any prior physical complications associated with substance abuse. This should include a discussion of prior episodes of cellulitis, abscesses, endovascular infections, including endocarditis, septic arthritis, or hepatitis. While these medical conditions may have resolved, it is useful to reiterate the adverse consequences of substance use to reinforce motivation for abstinence.

c. Develop a treatment plan

The physician should review the goals of the current treatment plan, review the patient's and physician's role in treatment and develop a treatment plan with the patient. Finally, the physician should discuss and review each component of the treatment plan. Treatment plans should document:

<u>Required Components of treatment plan</u>

1) Daily methadone maintenance
2) Weekly bottle pick-up
3) Monthly MM session attendance
4) Twice monthly urine sample collection and monitoring of toxicology results
5) Expression of the goal of maintaining abstinence

<u>Additional Components of treatment plan</u>

5) Attendance at self-help groups

A clear and readily understandable explanatory model of how and why treatment works may help the patient continue to benefit from the program. Therefore a rationale for each of the main treatment methods (i.e., methadone maintenance, MM visits, and NA or AA if appropriate) should be provided by the physician.

For instance, physicians should note how well the patient has been doing to date and discuss the rationale behind medical management in the treatment of patients with opiate dependence. A direct analogy to medical treatment for other chronic diseases including diabetes, hypertension and coronary artery disease should be made. Included in this explanation should be a discussion of the need for a multifaceted approach to treatment including modification of lifestyle, habits, self monitoring of symptoms and compliance with all components of treatment including, but not limited to pharmacotherapy. The physician should stress his/her role in helping the patient maintain abstinence at the same time recognizing that with medical management the patient is given increased responsibility.

d. Discuss the program features

The physician should discuss features of the program that can allow the patient to move ahead in their recovery, provide greater flexibility and acknowledge the patient's responsibility for their treatment.

The physician should also take this time to describe some ways in which MM will differ from a methadone clinic. The physician could describe the potential for increased flexibility. For instance, with advanced notice, the physician and staff may be able to alter the timing of bottle pick-up in response to a patient's request. The physician can also discuss ways in which the staff will attempt to arrange pick-up times in order to minimize waiting. For instance, a model for these weekly visits could be the quick blood pressure check whereby the patient comes for a specific office function and is able to bypass the usual check in and waiting procedures that frequently accompany a routine office visit.

The following expectations should also be reviewed at intake and as necessary. The patient is expected to: 1) attend all scheduled physician visits, 2) come to the office weekly to pick up methadone; 3) handle “take-home” medication in an appropriate manner 4) participate in clinical and research assessments as per protocol.

e. Discuss patient's experience with Narcotics Anonymous or Alcoholics Anonymous

In addition to "on site" treatment, the physician can review with the patient their experience with NA or AA meetings keeping in mind that some patients may have been able to maintain abstinence without NA or AA.

Physicians undergoing training in MM are strongly encouraged to attend a self-help group meeting specifically geared toward the opiate dependent patient, such as Narcotics Anonymous or Rational Recovery. If a referral is made to NA or AA, the following points are helpful to consider: 1) NA and AA provide an opportunity to meet others with similar problems and experiences, who will be supportive and helpful; 2) NA and AA provide a support system throughout the country and for as long as client decides to use it; 3) NA and AA provide a sense of meaning, friendships, closeness; 4) NA and AA encourage the patient to find meetings with members similar to the patient; 5) NA and AA address concerns about the spiritual aspects-recognizing and accepting that change is impossible in a personal vacuum that allows no one else to be involved; 6) NA and AA address concerns regarding success-many are successful without NA and AA, but research shows that those who remain involved on a long term basis, have a good chance of being successful; 7) note that some NA and AA groups do stigmatize people who take medications. This should not deter them from seeking a meeting which is accepting of the medication methadone. Patients should be referred to meetings that are sensitive to issues pertaining to drug dependent individuals who are on agonist maintenance treatment. Rational Recovery meetings are an alternative to NA or AA.

h. Advise abstinence and offer education about the negative consequences of continued drug use.

An explicit statement should always be made to the patient to abstain from all drugs, giving a clear rationale for why this is advisable.

i. Answer any questions the patient may have.

j. Dispense medication

2. Second and Subsequent Sessions

General Structure

Future visits should be devoted to (1) reviewing the patient's general progress, (2) assessing for indications of relapse, (3) reviewing major components of the treatment plan, (4) advice and goals for subsequent session. Follow-up physician encounters should explore and document specific information about the realms of substance use, medical, psychiatric, employment, social/family and legal status as included in the structured “MD Progress Note” (Appendix A). While these components of the subsequent visits are necessary, over time, as the patient

continues to do well in treatment, visits may also address diagnosis and management of other medical conditions, or preventive health issues (e.g., HIV prevention, smoking cessation).

A. Treatment protocols

a. Transport of Methadone

Methadone bottles will be made up for program participants on a weekly basis. Transport of methadone from CCCI to each physician's office will occur on regularly scheduled days within specific time periods. For example, transport and delivery of methadone to a specific physician's office may occur routinely on Tuesdays between the hours of 9 and 10 AM. A nurse accompanied by a member of CCCI program staff will transport bottles to each facility. One or two people at each site (preferably a nurse or physician) will be designated to be responsible for accepting the methadone bottles, cataloging their receipt, storing them in a locked cabinet, and returning empty bottles from the previous week.

b. Missed doses/No shows

All missed appointments should be reported to the MM physician. MM patients who miss a dose should be contacted by their physician's office and arrangements made for timely dosing. While missed doses and failure to make appointments for doses can occur for a variety of reasons, one should consider relapse or use of other substances and gently probe for information. Breath alcohol analysis and urine testing should be instituted, as indicated, if there are concerns over alcohol or illicit drug use.

c. Early or late arrivals

Patients who arrive early or late for medication will receive medication as soon as possible by the dispensing nurse or physician. As with other medical patients, unforeseen responsibilities and challenges (weather, traffic, child-care) may make prompt arrival difficult in some circumstances. MM physicians, and their offices, should try to accommodate patients and provide for the exchange of methadone bottles in a timely fashion. At the same time, patients may need to be reminded that physician's offices are busy and may not be able to accommodate them without a wait. A reminder to phone ahead to alert the office of changes in scheduling can be useful.

d. Schedule Changes - Dosing time flexibility

Physicians and their offices should attempt to be flexible to accommodate patient's requests for the timing of pick-up and drop-off of methadone bottles.

e. Methadone availability

Methadone transport schedules will allow for the delivery of methadone two days prior to dispensing. In the event that circumstances can be anticipated that will prevent transfer of methadone to patients on the scheduled dispensing day (i.e. severe weather warning), MM patients should be contacted to pick-up methadone early. In the event that methadone can not be delivered to the MM physician's office at the scheduled time, CCCI should contact the MM physician's office to clarify alternative arrangements. If unanticipated conditions require a physician's office to be closed on patient's pick-up day and alternative arrangements (i.e. early pick-up) have not been made, the patient may receive their daily dose of methadone from CCCI.

f. Charts

Physicians will be provided with a CCCI chart for all study patients. This will contain information about the patients prior treatment and an updated Treatment Plan Review. All MM Encounter forms and urine toxicology results should be placed in this chart. This "Connecticut Counseling" chart should be stored in a separate area from other medical records with access limited only to those clinicians (nurses and physicians) who are providing care to the patient. This will help ensure patient confidentiality throughout the treatment period. Progress notes and other chart forms will be forwarded to CCCI on a monthly basis for review by the Medical Director and Program Director.

g. Phone Calls

The MM physician will be available to the patient for telephone calls regarding general concerns and questions. The patient should also be instructed that if his/her physician is not available, there is an emergency number he/she can call to contact a member of the physician's covering team 24 hours a day.

h. After hours phone triage

MM patient phone calls after office hours should be triaged according to the nature of the call and the patient's long term primary care relationship. For instance, all calls regarding methadone dose, side effects, and drug interactions will be handled by the MM physician (if they happen to be on call) or referred to Connecticut Counseling Centers, Inc.. Phone calls that

are unrelated to methadone will be handled by the on call physician (if patient's primary care physician is within the office group) or referred to the patient's primary care provider.

i. Request for lab results

Patients may request results of their urine tests for legal, employment, or personal reasons. These requests can be handled by providing the results directly to the patient.

j. Discussion of positive urine results

Any patients whose urine is positive for cocaine, benzodiazepines, or opiates will be required to produce another specimen the next day. Two positive urine results will necessitate termination from the study, transfer of the patient back to CCCI, and loss of Level 5 status for the patient.

a. Breath alcohol analyzer use

If needed, a breath alcohol analysis unit will be provided for each site along with instructions on proper use.

b. Clinical Deterioration

Patients who develop potentially life-threatening medical and/or psychiatric problems will be evaluated by an independent physician to assess their treatment needs and whether they can continue safely in the study; patients who cannot be maintained safely in the clinical trial will be referred for appropriate treatment. Reports of suicidal or homicidal ideation should be dealt with via appropriate evaluation and referral (i.e. Crisis Team, psychiatric care) based upon immediate clinical needs. Contact should be made with one of the supervising program physicians (Drs. Fiellin, O'Connor, or Schottenfeld) and the Program Director of CCCI.

c. Referral to community agencies

If it appears that the patient has not been able to satisfy basic his/her needs (e.g., housing, child care) or to address practical issues (e.g., assistance with legal matters), the physician will provide a menu of options including referral to 1) a social worker 2) a local, state or community agency, or 3) to social services at CCCI.

d. Suspected relapse

If the clinician suspects relapse in a patient, the patient should be asked about recent illicit drug use, cravings, or psychosocial stresses. Frank discussion of the clinician's reasons for concern may help clarify issues and should be followed by a random witnessed urine collection.

e. Intoxicated patients

If a patient presents for methadone while intoxicated or smelling of alcohol, a breath analysis for alcohol must be performed.

Note: It is rare for patients who have demonstrated stability in methadone maintenance to present for medication while intoxicated. Therefore, any occurrence of this should be investigated by the MM physician and an evaluation for relapse should be performed. Intoxicated patients will not receive methadone or take home doses and risk study termination.

Patients with a positive breath alcohol result should be advised not to drive and offered a cab or directed to the nearest bus station.

p. Use of other medications

Patients should be advised that the use of any prescribed medications should be reported to the physician as soon as possible. In the case of a need for another medication (e.g., antibiotic for an acute febrile bacterial illness), the medication, dose, and reason for prescribing, should be reported and recorded.

Patients may use over the counter medication, such as aspirin or acetaminophen, under ordinary circumstances, but the use of prescription medication should be undertaken only after consultation with the physician.

q. Failure to return methadone bottles

If patients do not return their weekly supply of bottles they can not receive take home doses of methadone. Patients should receive one observed dose of methadone and must return the following day with empty bottles from the prior week to receive take home doses.

A. Transfer

A significant provider-patient relationship will likely develop over the time course of the study. In light of this, discussion of transfer should occur and will likely be an important element of the last several sessions. Discussion should begin no later than 8 weeks prior to transfer, and by 4 weeks prior, should be an element in every scheduled visit. A sensitively directed inquiry and guided discussion that permits the patient to express his/her feelings and ideas about having participated in the study, and attitude towards the physician is a necessary component of the general therapeutic process.

III. Summary

This manual is intended to be used by physicians as guide for the MM of methadone maintenance in primary care settings with opiate dependent individuals. The manual describes the general and specific aims of MM and details specific procedures for the initial/intake and second sessions. However, the manual is only meant as a guide for trained physicians. Training seminars, supplemental readings, and ongoing clinical review are crucial to the successful implementation of MM.

Appendix A

Office-based Methadone Project
MD Progress Note

Client Name _____ ID# _____

Date ___/___/___ Week# ___ ☐ No show

Scheduled Visit Time _____ Actual Visit Time _____

Medical Management

Heroin/Cocaine or other illicit drug use since last visit?

_____
_____
_____

Symptoms or signs that might imply relapse? (Changes in mood, physical appearance)

_____
_____
_____

Since the last visit, are there any problems with the following:

		If yes, explain
Drug Use	☐ Yes ☐ No	_____
Alcohol Use	☐ Yes ☐ No	_____
Psychiatric	☐ Yes ☐ No	_____
Medical	☐ Yes ☐ No	_____
Employment	☐ Yes ☐ No	_____
Social/Family	☐ Yes ☐ No	_____
Legal	☐ Yes ☐ No	_____

Any new problem to add to Treatment Plan Review ☐ Yes ☐ No _____

_____

Plan to address any new problem _____

_____

_____

Participation in Narcotics Anonymous or
Alcoholics Anonymous since last visit? ☐ Yes ☐ No

Length of session _____

_____
Physician Signature

Appendix B

Bottle Log

Patient	**Date received**	**# bottles received from CCCI**	**Dose**	**Signature (MM Nurse)**	**Date returned**	**# bottles returned to CCCI**	**Condition** **Good** **Damaged**	**Signature (CCCI Nurse)**

Medical Maintenance Project
